

**REMARKS**

**I. Status of the claims**

Claims 14-23 and 26-29 are under examination in this application. No amendments have been made to the claims in this Supplemental Response.

**II. The rejections under 35 U.S.C. § 103(a)**

The Examiner has rejected claims 14-23 and 26-29 under 35 U.S.C. § 103(a) as being unpatentable over Dittmar et al (U.S. 4,185,106) in view of Squiquera et al. (July 1996), Shoshan (WO 96/290455) and Thorel (FR 2,685,867). Applicants responded to these rejections with the arguments found at pages 11-18 of the Amendment filed on September 7, 2006, and wish to reiterate that they stand on those arguments and believe that a *prima facie* showing of obviousness has not been made by the Office.

Nonetheless, in the interests of hastening prosecution, Applicants submit the Declaration of Kevin Kriel, Senior Project Manager at Medicis, who is responsible for the sales and marketing of Loprox Shampoo. His declaration attests to the continued and growing commercial success of Loprox Shampoo. As is clear from Paragraph 1 of the Kriel Declaration, Loprox Shampoo is covered by claims 14, 15, 17-20, 22, and 23. Further, as Mr. Kriel attests in Paragraph 7, Loprox Shampoo is a composition comprising a 1-hydroxy-2-pyridone (e.g., ciclopirox), having a pH of 4.5 to 6.5, a surfactant and no additional active compounds. These are the features of the claimed invention and it is this claimed composition that has continued to grow in sales (up 13%) from January 2005 to January 2006 in a flat or slightly declining market. See Kriel Declaration, Paragraphs 8 and 9. Loprox Shampoo is a prescription shampoo and this

continued growth in sales has occurred despite the presence in the market of competitive, mostly less expensive, prescription products. *Id.*, Paragraphs 6 and 7.

This 13% increase in market share in an adverse market is an indicator of commercial success and would not have occurred unless physicians and patients judged Loprox Shampoo, even at a premium price, to be a more effective treatment for seborrheic dermatitis than the competitive prescription shampoos already on the market. *Id.*

The continuing increase in market share of Loprox Shampoo, which is FDA approved for the treatment of seborrheic dermatitis, is evidence of commercial success and additional evidence of the non-obviousness of claims 14-23. Accordingly, the § 103(a) rejections of the pending claims should be withdrawn.

If there is any fee due in connection with the filing of this Amendment, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: September 22, 2006

By: Maryann I. English (Reg. No. 52,138)  
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**Attachment:**

- (1) Declaration of Kevin Kriel (Exh. A).